IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

PERNIX IRELAND PAIN DAC and PERNIX THERAPEUTICS, LLC, Plaintiffs, v. ALVOGEN MALTA OPERATIONS LTD., Defendant.	REDACTED - PUBLIC VERSION C.A. No. 16-139-WCB [redacted]

BRIEF IN OPPOSITION TO PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT OF INFRINGEMENT AND REQUEST FOR RULE 56(f)(1) FINDING OF NON-INFRINGEMENT

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Defendant Alvogen Malta Operations Ltd. ("Alvogen") respectfully requests that the Court deny Plaintiffs Pernix Ireland Pain DAC's and Pernix Therapeutics, LLC's (collectively, "Pernix") Motion for Summary Judgment of Infringement. Alvogen further requests that the Court enter summary judgment of non-infringement under Federal Rule of Civil Procedure 56(f)(1) because Alvogen will not induce infringement of any of the Asserted Claims.

I. NATURE AND STAGE OF THE PROCEEDINGS

This is a patent action under the Hatch-Waxman Act related to Alvogen's submission of ANDA No. 206986 for hydrocodone extended-release capsules. Pernix asserts that Alvogen will induce infringement of claims 1-4, 11, 12, 17 and 19 of the U.S. Patent No. 9,265,760 ("the '760 patent") and claim 1 of the 9,339,499 ("the '499 patent") (collectively, "the Asserted Claims") through the sale of Alvogen's ANDA Product and corresponding product label ("Alvogen's Label"). Alvogen submits this brief in opposition to Pernix's Motion for Summary Judgment of Infringement (D.I. 118), and to request the Court enter judgment of non-infringement.

II. SUMMARY OF THE ARGUMENT

There are no genuinely disputed material facts preventing entry of summary judgment of non-infringement in Alvogen's favor. Because the facts Pernix relies on for its infringement positions are insufficient as a matter of law, Alvogen requests that the Court enter summary judgment of non-infringement under Federal Rule of Civil Procedure 56(f)(1) with respect to all Asserted Claims.[1]

1. Alvogen does not induce infringement of claims 1-4 and 11 of the '760 patent because there is no direct infringement of these claims. The claims require a physician and a

[1] If the Court declines to enter summary judgment for Alvogen, there are at minimum genuine issues of fact that prevent entry of summary judgment for Pernix.

patient to each perform separate method steps, and Pernix's own evidence and expert witnesses demonstrate the fact that physicians do not condition continued treatment upon patients' performance of the "administering" method step.

a. Although Pernix now argues that these claims include only a single method step and therefore require only a single actor, Pernix's own contentions, expert reports and prior arguments to the Court flatly contradict Pernix's new position.[2] Pernix's single-actor theory is also inconsistent with the Court's claim construction order, which establishes that a physician's prescription of the claimed starting dose and a patient's self-administration of that starting dose are separate method steps.

b. Pernix's alternative joint infringement theory under the Akamai "conditions" standard also fails because physicians in fact do not condition the continuation of treatment (a benefit or activity) upon a patient's self-administration of a starting dose as prescribed (method step). For example, Pernix's own expert witness testified that physicians may continue treatment despite patients failing to comply with prescribing directions, even when patients exhibit "aberrant behavior."

2. Alvogen does not induce infringement of any of the Asserted Claims because Alvogen's Label, which forms the sole basis of Pernix's allegations of intentional inducement, does not encourage, recommend or promote the [redacted]. Additionally, Alvogen does not induce infringement

[2] Alvogen has moved to strike as untimely Pernix's argument that patients directly infringe by performing all of the limitations of claims 1-4 and 11 of the '760 patent. See Alvogen Malta Operations LTD.'s Motion to Strike and Exclude Pernix's Late-Disclosed Infringement Theory, D.I. 125 (filed Mar. 26, 2018).

of claims 1-4 and 11 of the '760 patent because Alvogen's Label does not encourage, recommend or promote the [redacted]. At most, Alvogen's Label [redacted], which as a matter of law does not establish inducement.

III. STATEMENT OF FACTS

A. Asserted Patents and Claims

Claim 1 of the '760 patent, from which claims 2-4 and 11 depend, require "administering to [a] patient having mild or moderate hepatic impairment a starting dose of an oral dosage unit having hydrocodone bitartrate as the only active ingredient" (referred to herein as the "administering" limitation). The Court construed the term "administering" to mean "delivering into the body," rejecting Pernix's claim construction argument that a physician's prescription constitutes "administering" a drug. (D.I. 85 at 1.) As the "administering" limitation recites an "oral dosage unit," this limitation requires ingestion of the dosage unit, an act performed by a patient rather than a physician.

These claims also require that "the starting dose is not adjusted relative to a patient without hepatic impairment" (referred to herein as the "non-adjustment" limitation). The Court construed "wherein the starting dose is not adjusted relative to a patient without hepatic impairment" to mean "[t]he dose prescribed to a patient with mild or moderate hepatic impairment when initiating treatment is not reduced due to that hepatic impairment relative to the dose prescribed to a patient without hepatic impairment when initiating treatment." (Id. at 2.)

Claims 12, 17 and 19 of the '760 patent, and claim 1 of the '499 patent, are similar to claim 1 of the '760 patent, but recite pharmacokinetic properties of the administered dosage unit rather than requiring that the starting dose is not adjusted relative to a patient without hepatic

impartment. (See Ex. A to Opening Brief in Support of Pernix's Motion for Summary Judgment of Infringement (D.I. 120) ('760 patent, claims 12, 17 and 19); Ex. B to D.I. 120 ('499 patent, claim 1).)

B. Alvogen's Label

Alvogen's Label contains [redacted] identified by Pernix in its opening brief. (D.I. 120 at 5.) Pernix cites no evidence of intent to induce infringement of the Asserted Claims, or evidence that Alvogen would in fact induce infringement, beyond these references in Alvogen's Label. Notably, [redacted]

IV. ARGUMENT

A. Legal Standards

1. Inducement of Joint Infringement

Induced infringement is predicated on the direct infringement of a third party; where there is no direct infringement, there cannot be induced infringement. See Limelight Networks, Inc. v. Akamai Techs., Inc., 134 S. Ct. 2111, 2117-18 (2014). Direct infringement of a method claim in turn requires all claim steps to be performed by or attributable to a single entity. Id.

The Federal Circuit attributes performance of a method step by a third party to an accused infringer where the accused infringer exerts "control or direction" over the third party. See Muniauction, Inc. v. Thomson Corp., 532 F.3d 1318, 1330 (Fed. Cir. 2008). "[M]ere 'arms-length cooperation' will not give rise to direct infringement by any party" under the "control or direction" standard. Id. at 1329. The standard is satisfied, however, where the accused infringer

"conditions participation in an activity or receipt of a benefit upon performance of a step or steps of a patented method and establishes the manner or timing of that performance." Akamai, 797 F.3d at 1023.

2. Specific Intent to Induce Infringement

"Inducement requires a showing that the alleged inducer knew of the patent, knowingly induced the infringing acts, and possessed a specific intent to encourage another's infringement of the patent." Vita-Mix Corp. v. Basic Holding, Inc., 581 F.3d 1317, 1328 (Fed. Cir. 2009). Intent to induce infringement can be demonstrated by circumstantial evidence, but "where a product has substantial non-infringing uses, intent to induce infringement cannot be inferred even when the defendant has actual knowledge that some users of its product may be infringing the patent." Warner-Lambert Co. v. Apotex Corp., 316 F.3d 1348, 1365 (Fed. Cir. 2003); see also Acorda Therapeutics Inc. v. Apotex Inc., No. 07-4937, 2011 WL 4074116, at *19-20 (D.N.J. Sept. 6, 2011), aff'd, 476 F. App'x 746 (Fed. Cir. 2012) (Where there is "a substantial non-infringing use for [a] product, . . . more than the mere sale of the product is required" to establish intent to induce infringement.). "[N]on-infringing uses are substantial when they are not unusual, far-fetched, illusory, impractical, occasional, aberrant, or experimental." Vita-Mix, 581 F.3d at 1327.

Where a label merely provides information that describes infringing uses or permits physicians to infringe, but does not include instructions that encourage infringement, the label is not evidence of specific intent to induce infringement. See Takeda Pharm. U.S.A., Inc. v. West-Ward Pharm. Corp., 785 F.3d 625, 630-31 (Fed. Cir. 2015); Acorda, 2011 WL 4074116, at *19-20; Shire LLC v. Amneal Pharm., LLC, No. 11-3781, 2014 WL 2861430, at *4-5 (D.N.J. June 23, 2014).

3. Summary Judgment Under Federal Rule of Civil Procedure 56(f)(1)

Federal Rule of Civil Procedure 56(f)(1) provides that, "[a]fter giving notice and a reasonable time to respond, the court may . . . grant summary judgment for a nonmovant[.]" "Where one party has invoked the power of the court to render a summary judgment against an adversary, Fed. R. Civ. P. 54(c) and 56, when read together, give the court the power to render a summary judgment for the adversary if it is clear that the case warrants that result, even though the adversary has not filed a cross-motion for summary judgment." Talecris Biotherapeutics, Inc. v. Baxter Int'l Inc., 510 F. Supp. 2d 356, 362 (D. Del. 2007).

B. Alvogen Does Not Induce Infringement of Claims 1-4 and 11 of the '760 Patent Because There Is No Direct Infringement of These Claims.

1. Claims 1-4 and 11 of the '760 Patent Contain a Claim Step Performed by a Patient and at Least One Claim Step Performed by a Physician.[3]

Until Pernix filed its Motion for Summary Judgment of Infringement, Pernix itself contended that the "administering" and "non-adjustment" limitations of claims 1-4 and 11 of the '760 patent contain distinct claim steps performed by separate actors and advanced only a theory of joint infringement regarding these claims. For example, Pernix's most recent infringement contentions assert that these claims are infringed when the "administering" and "non-adjustment" steps are performed by a patient and a physician, respectively:

- Regarding the "administering" step:
  - "Alvogen's Draft Label [redacted]

[redacted]

[3] As noted above, Alvogen has moved to strike as untimely Pernix's argument that patients directly infringe by performing all of the limitations of these claims. This section explains why Pernix's single-actor infringement theory also fails as a matter of law.

[redacted]

- Regarding the "non-adjustment" step:
  - "Alvogen's Draft Label [redacted]

Pernix's contentions also rely exclusively on the Akamai "conditions" standard for joint infringement for each of these limitations, further establishing Pernix's own view that practicing the claims requires multiple actors:

> Physicians direct and/or control their patients' administration of a starting dose of Alvogen's proposed generic product in such a manner as to condition the receipt of treatment on the patients' administration of the prescribed starting dose. Further, the physician establishes the manner and timing of the patients' administration of the starting dose.

(Id. at 2.) Pernix's expert witness Dr. Gudin confirmed this understanding of the claims in his in infringement expert report, stating that [redacted], ***the physician and patient jointly practice [claim 1 of the '760 patent]***." (Opening Infringement Expert Report of Jeffrey Gudin, M.D., ¶ 77 (dated Nov. 22, 2017) (emphasis added) (attached as Exhibit 2).) Dr. Gudin also relied on the "conditions" standard, arguing that "[t]he patient's receipt of the prescribed dose of drug (through filling the doctor's prescription) is conditioned upon the understanding that the patient will use the drug exactly as prescribed, and it is the physician who dictates the manner and timing of the patient's self-administration of the drug." (Id. at ¶ 74.)

Moreover, during claim construction Pernix affirmatively represented to the Court that

the "non-adjustment" limitation "is an essential step in the claimed method of treatment [without which] doctors practicing the claimed treatment methods would adjust the starting dose, as they do for other opioid products, defeating the central purpose of the claimed inventions." (D.I. 65, at 1.) After persuading the Court to adopt Pernix's claim construction for the "non-adjustment" limitation, including by arguing that it is a claim step, Pernix should not now be heard to argue that the limitation is not a claim step.

Far from merely affecting "how the administration step is performed," as Pernix now contends for the first time (D.I. 120 at p. 12), the "non-adjustment" limitation as construed requires a physician to prescribe a dosage unit to a patient with hepatic impairment as part of the claimed method: "[wherein] the dose prescribed to a patient with mild or moderate hepatic impairment when initiating treatment ***is*** not reduced . . . ." D.I. 85 at 2 (emphasis added). The Court's construction explicitly recites a physician's act of prescribing the dosage unit by using the present tense verb "is." The Court adopted this construction "because [it] effectuates the court's finding that the phrase is a limitation" and "not just a mental step." Id. at 3. Under this construction, it is apparent that both the patient and the physician must perform separate method steps to practice the claims.

Pernix relies on a single, readily distinguishable case for its new contention that the "non-adjustment" limitation is not a method step. (See D.I. 120 at 12-13 (citing Orexigen Therapeutics, Inc. v. Actavis Labs. FL, Inc., 282 F. Supp. 3d 793 (D. Del. 2017).) Unlike the "non-adjustment" limitation in the present case, the limitation at issue in Orexigen facially referred to an event that occurred in the past: "an individual who ***has been*** diagnosed as suffering from overweight or obesity." Orexigen, 282 F. Supp. 3d at 812 (emphasis added). Thus, the court found that the claim did not recite a separate diagnosing claim step but instead

required that "the individual [was] already [] diagnosed prior to the method being performed." Id.

Courts have found claim language similar to the "non-adjustment" limitation using the word "is" to signify a claim step. In Desenberg, 392 F. App'x at 870, for example, the Federal Circuit held that the claim limitation "wherein a service ***is performed*** by the user or the provider . . ." included a method step, stating that it "clearly requires the participation of" an additional entity. (emphasis added.) Similarly, in e2Interactive, Inc. v. Blackhawk Network, Inc., No. 09-629, 2012 WL 13000393, at *2, *19 (W.D. Wis. Jan. 17, 2012), the court found the claim limitation "wherein the value ***is added*** to the pre-existing customer account by the specific provider" to include a claim step. (emphasis added.)[4] Accordingly, unlike the limitation at issue in Orexigen, the "non-adjustment" limitation is a separate method step performed by a physician.

2. Physicians Do Not "Condition" Continued Treatment on Patients' Performance of the "Administering" Step.

Induced infringement must be predicated on direct infringement, which in turn requires that all of the steps of a claimed method are performed by or attributable to a single entity. Limelight, 134 S. Ct. at 2117-18. Pernix alleges that there is direct infringement under the Akamai "conditions" standard because "physicians . . . condition continued treatment for chronic pain (i.e., receipt of a benefit) on the patient administering Alvogen's ANDA Product as prescribed (i.e., performance of a claim step)." (D.I. 120 at 14.) But the only evidence Pernix offers demonstrates the opposite, namely that the receipt of continued treatment is *not* conditioned on the patient administering the drug "as prescribed."

Pernix's sole evidence of conditioning is a form template titled "Consent for Chronic

[4] Also similar to the "non-adjustment" limitation here, in both Desenberg and e2Interactive, the limitations at issue began with "wherein" and did not include a gerund (e.g., prescribing).

Opioid Therapy." (Id. at 14-15, Ex. H ("Consent Form").) By its own terms, the Consent Form does not condition continued treatment on the patient's adherence to prescribing directions. For example, Pernix quotes select portions of the following paragraph from the form:

> I have been informed by my physician that the initiation of a narcotic/opioid medication is a trial. Continuation of the medication is based on evidence of benefit to me from, associated side effects of, and compliance with instructions on, usage of the medication. I have also been informed by my physician that continuation and any changes in dosage of the medication will be determined by pain relief, functional improvement, side effects, and adherence to usage restrictions. Lack of significant improvement, the development of adverse side effects, or other considerations ***may lead my physician to discontinue this treatment*** or to change dosage.

(Ex. H (Consent Form) to D.I. 120 at 1 (emphasis added.) This does not provide that treatment will categorically be discontinued if the patient fails to adhere to prescribing directions. Rather, it merely informs the patient that "compliance with instructions on[] usage of the medication" and "adherence to usage restrictions" are among a number of different factors and considerations that "may" lead to discontinuation. Furthermore, adherence to prescribing directions is specifically addressed in a separate paragraph that Pernix does not mention in its brief:

> I will take this/these medication(s) only as prescribed and I will not change the amount or dosing frequency without authorization from my physician. I understand that unauthorized changes may result in my running out of medications early, ***and early refills may not be allowed.***

(Id. at 2 (emphasis added).) Notably, this does not provide that failure to adhere to prescribing directions will lead to discontinuation, but only that "early refills may not be allowed."

The all-caps paragraph at the end of the form that Pernix quotes is also non-categorical:

> I UNDERSTAND AND AGREE THAT FAILURE TO ADHERE TO THESE POLICIES WILL BE CONSIDERED NONCOMPLIANCE AND ***MAY RESULT IN CESSATION OF OPIOID PRESCRIBING BY MY PHYSICIAN*** AND POSSIBLE DISMISSAL FROM THIS CLINIC.

(Id. at 2 (emphasis added).) Moreover, given that adherence to prescribing directions is

specifically addressed without the threat of possible discontinuance earlier in the form, the "policies" referred to in this paragraph are more likely a reference to serious and potentially illegal actions captured in statements such as "I will not share, sell or otherwise permit others to have access to these medications." (Id.)

Finally, Pernix mischaracterizes the Florida statute mandating that certain physicians use a written "controlled substance agreement." (D.I. 120 at 15.) The statute does not require that the "agreement must state that non-compliance may result in discontinuation of mediation" as Pernix states. (Id.) Rather, it requires the agreement to outline, among other things, "[p]atient compliance and reasons for which drug therapy may be discontinued, such as a violation of the agreement." (Id., Ex. I at 3 (emphasis added).) The "reasons" are not specified. Of course, the statute employs the same non-categorical "may" as the Consent Form.

Dr. Gudin, Pernix's expert, confirmed the non-categorical nature of physicians' prescribing practices reflected in the Consent Form. He testified under oath that documents such as the Consent Form are "not contracts" (Gudin Dep. Tr. at 67:14-68:3 (attached as Exhibit 3).) and that physicians may well continue treatment even if a patient fails to comply with prescribing directions:

> [T]here is certainly any number of reasons that the clinician may tolerate, for lack of a better word, need for early refills, losing prescriptions, escalating the medications without permission. Those may indeed be reasons for the doctor to discontinue prescribing, but patients will lose prescriptions. To me this . . . paragraph [of the consent form] is not categorical . . . , but just a list of reasons that the doctor may elect to discontinue prescribing.

(Id. at 69:11-24.) In fact, Dr. Gudin testified that even if a patient shows signs of abuse, the patient may receive a warning rather than being cut-off from continued opioid treatment: "[I]f there is any signs of aberrant behaviors, [the physician or] one of the other staff [] reminds [the patient] of the content of [the consent form]." (Id. at 56:2-12.) Thus, Pernix's own expert

admits that the patient's performance of a method step (taking the medication as prescribed) is merely a factor that *might* impact subsequent prescribing decisions. It is not a condition of such treatment.

The Eli Lilly case Pernix relies on is readily distinguishable on this basis. The claims there required the administration of folic acid (which in practice is performed by patients) followed by administration of the toxic chemotherapy agent pemetrexed (which in practice is administered by healthcare professionals). Eli Lilly & Co. v. Teva Parenteral Medicines, Inc., 845 F.3d 1357, 1362 (Fed. Cir. 2017). The purpose of administering folic acid prior to chemotherapy was to mitigate the potentially life-threatening toxicity of the cancer treatment. Id. at 1365. The Federal Circuit found that because the folic acid pretreatment was critical for patient safety, no physician would ever proceed with the chemotherapy treatment knowing that a patient had failed to take the folic acid. Id. at 1366 (citing expert testimony that folic acid pretreatment was "an absolute requirement" and that "if a physician realizes that a patient did not follow his or her instructions to take folic acid, then the doctor will not give the pemetrexed" as a categorical matter) (internal quotations omitted). Thus, the Federal Circuit concluded that "the evidence regarding the critical nature of folic acid pretreatment and physicians' practices support a finding that physicians cross the line from merely guiding or instructing patients to take folic acid to conditioning pemetrexed treatment on their administration of folic acid." Id.

Here, by contrast, Dr. Gudin testified that documents like the Consent Form are not "categorical," and that physicians continue treatment despite patients failing to comply with prescribing directions, even when exhibiting "aberrant behavior." (See Ex. 3, at 56:2-12.) Thus, the evidence mandates the conclusion that, with respect to Alvogen's ANDA Product, physicians will *not* "cross the line from merely guiding or instructing patients" to "conditioning" continued

treatment on the patient's administering the drug exactly as prescribed. See Eli Lilly, 845 F.3d at 1368 ("Our holding today does not assume that patient action is attributable to a prescribing physician solely because they have a physician-patient relationship.").

Finally, although not a necessary consideration for the Court to enter judgment of non-infringement on claims 1-4 and 11 of the '760 patent, it is undisputed that physicians cannot know whether a patient is taking an extended-release opioid exactly as prescribed. For example, Dr. Gudin testified that [redacted]. (Id. at 71:20-72:3.) He then testified that, [redacted] Pernix attempts to dismiss this fact by pointing to the Federal Circuit's statement that conditioning "does not necessarily require double-checking another's performance . . . ." Eli Lilly, 845 F.3d at 1366 (Fed. Cir. 2017). The salient point, however, is that unlike in Eli Lilly where the folic acid pretreatment could in principle be verified by blood tests, physicians know that verification of adherence to the prescribing directions for Alvogen's ANDA Product is impossible. Conditioning must require at least the possibility of verifying that the condition is met. Certainly, Alvogen is not aware of any case where a court has found that the conditioning test was satisfied where verification was impossible.

For the foregoing reasons, Pernix's motion for summary judgment of infringement of claims 1-4 and 11 of the '760 patent should be denied, and the Court should enter summary judgment of non-infringement for these claims.

C. Alvogen Does Not Intentionally Induce Infringement of Any Asserted Claim Because Alvogen's Label Does Not Recommend, Promote or Encourage Treatment of [redacted], Let Alone [redacted].

Summary judgment of non-infringement should also be entered in Alvogen's favor because there is no genuine issue of fact that Alvogen does not induce infringement of any of the Asserted Claims. Pernix's alleged evidence of induced infringement is derived entirely from Alvogen's Label, which [redacted]. Additionally, Alvogen's Label does not induce infringement of claims 1-4 or 11 of the '760 patent because it [redacted].

As an initial matter, "where a product has substantial noninfringing uses, intent to induce infringement cannot be inferred" from the mere sale of the product. Warner-Lambert, 316 F.3d at 1365. It is undisputed that Alvogen's ANDA Product can be used to [redacted]. Accordingly, Pernix must rely on affirmative evidence, such as the statements in Alvogen's Label, to establish intentional inducement of infringement.

Where a plaintiff relies on a product label to establish inducement, it is not sufficient that the label is "[m]erely describing an infringing mode . . . ." Takeda, 785 F.3d at 630-31. Rather, the label must be "recommending, encouraging, or promoting an infringing use, or suggesting that an infringing use should be performed." Id. (internal quotation marks and citations omitted); see also In re Depomed Patent Litig., No. 13-4507, 2016 WL 7163647, at *24 (D.N.J. Sept. 30, 2016) (same). Here, the statements in Alvogen's Label that Pernix points to are [redacted] (D.I. 120 at 16.)

1. Alvogen's Label Does Not Intentionally Induce the [redacted].

a. The Statements in Alvogen's Label Directed to the [redacted] Are Not Evidence of Intentional Inducement of Infringement.

To demonstrate that Alvogen's Label will induce the use of Alvogen's ANDA Product in [redacted], Pernix relies on [redacted] Pernix contends that these statements [redacted] The Federal Circuit has repeatedly stated, however, that where there are substantial non-infringing uses, as there are here (namely, the treatment of patients without hepatic impairment), mere knowledge that some users will infringe the asserted claims does not establish intentional inducement of infringement. See, e.g., Warner-Lambert, 316 F.3d at 1365; Vita-Mix, 581 F.3d at 1329.

Unsurprisingly, none of the cases Pernix cites support its contention. In Eli Lilly, 845 F.3d at 1369, the court found induced infringement because the label included "repeated instructions and warnings regarding the importance of and reasons for [performing the claimed method]." The court nowhere suggested that intentional inducement of infringement can be established merely by arguing that "some physicians would infringe claims" as Pernix suggests.

Similarly in AstraZeneca LP v. Apotex, Inc., 633 F.3d 1042, 1060 (Fed. Cir. 2010), the court affirmed a preliminary injunction finding that inducement was likely to be proved at trial where, unlike here, there was insufficient evidence to establish substantial non-infringing uses and the label characterized the relevant activity as "desirable" "in all patients." And in Sanofi v. Glenmark Pharm. Inc., USA, 204 F. Supp. 3d 665, 675 (D. Del. 2016), the court found induced infringement because the Indications and Usage section of the label directed the reader to the clinical studies section, which encouraged infringement by disclosing that the only population shown to benefit from the drug met the claimed parameters. In each of these cases, the finding of intentional inducement of infringement relied on the instructions in the label, not on the fact that some physicians would infringe.

b. The Statements in Alvogen's Label Relating to [redacted] Are Not Evidence of Intentional Inducement of Infringement.

In its claim chart, Pernix further cites to sections in the label [redacted]

Pernix offers no argument or explanation as to how [redacted] induce administration of Alvogen's ANDA Product to [redacted]. In fact, these statements do not demonstrate intentional inducement because they are, at most, "[m]erely describing an infringing mode. . . ." without "recommending, encouraging, or promoting an infringing use, or suggesting that an infringing use should be performed." Takeda, 785 F.3d at 630-31 (internal quotation marks and citations omitted); see also Eli Lilly, 845 F.3d at 1368.

Courts have found that similar statements in proposed labels did not demonstrate inducement. In Acorda, 2011 WL 4074116, at *14, for example, the claims were directed to "a method of administering [a multiparticulate drug] to patients with food." The plaintiff argued that the label induced infringement because it described the effects of food on the pharmacokinetics of the drug, including by providing pharmacokinetic data for patients who had taken the drug with food. Id. at *17. The Court disagreed, finding that these passages did not "direct any action on the part of any physician, but merely call[ed] attention to the pharmacokinetics section and the differences between . . . the fed and fasted states." Id. Accordingly, the Court held that the proposed label did "not suggest that capsules [containing multiparticulate drug] be used in the fed state" and that the plaintiff had "not shown that this label will induce infringement" of the asserted claims. Id. at *18 (citing Vita-Mix, 581 F.3d at 1324-26). Just as the proposed label in Acorda merely described the effect of food on treatment without encouraging administration of the claimed drug with food, Alvogen's Label merely describes [redacted].

Similarly, in Shire, 2014 WL 2861430, the claimed method required that the drug be taken with food. Id. at *4. As evidence of inducement, the plaintiffs pointed to a passage in the "Dosage and Administration" portion of the label "that the products may be taken 'with or without food.'" Id. at *5. The Court rejected this as evidence of inducement:

> The problem is that the statement that the medication may be taken with or without food cannot be reasonably understood to be an instruction to engage in an infringing use. As Defendants contend, it is indifferent to which option is selected. At most, it may be understood to permit an infringing use, but permission is different from encouragement.

Id. Similarly, Alvogen's Label is [redacted].

Pernix cites Eli Lilly for the proposition that [redacted] The label in Eli Lilly, however, provided direct and fervent instructions for patients to perform the claim step of administering folic acid, stating: "Instruct patients on the need for folic acid . . . ."; "[T]he patient] must also take folic acid . . . ."; and "It is very important to take folic acid . . . ." Eli Lilly, 845 F.3d at 1367. Alvogen's Label, by contrast, at most [redacted] And as Eli Lilly explains, "[t]he question is not just whether [those] instructions describ[e] the infringing mode, . . . but whether the instructions teach an infringing use such that we are willing to infer from those instructions an affirmative intent to infringe the patent." Id. at 1368 (quoting Takeda, 785 F.3d at 631).[5]

2. Alvogen Does Not Intentionally Induce [redacted]

Alvogen will also not induce infringement of claims 1-4 and 11 of the '760 patent for the

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[5] The cases Pernix cites in its Legal Standards section are similarly distinguishable. In Sanofi v. Watson Labs. Inc., 875 F.3d 636, 645 (Fed. Cir. 2017) and Braintree Labs., Inc. v. Breckenridge Pharm., Inc., 688 F. App'x 905, 909 (Fed. Cir. 2017), the proposed labels at issue stated in the "Indications and Usage" section that the drug is indicated for an infringing use. [redacted] In AstraZeneca LP v. Apotex, Inc., 633 F.3d 1042 (Fed. Cir. 2010), there was insufficient evidence to establish substantial non-infringing uses and the label characterized the relevant activity as "desirable" "in all patients." In Eli Lilly & Co. v. Actavis Elizabeth LLC, 676 F. Supp. 2d 352, 378 (D.N.J. 2009), aff'd in part, rev'd in part, 435 F. App'x 917 (Fed. Cir. 2011), the defendants' only defense was that FDA forced them to include the offending language in their label. And in Wyeth v. Sandoz, Inc., 703 F. Supp. 2d 508, 520 (E.D.N.C. 2010), the court found that the asserted claims covered every approved use of the accused ANDA product. Here, the asserted claims only cover a fraction of the approved uses – the uses of the drug in which the patient treated has mild or moderate hepatic impairment.

independent reason that Alvogen's Label does not encourage, recommend or promote administering Alvogen's ANDA Product to [redacted].[6] Pernix again relies on [redacted] This is insufficient.

The statement that [redacted] facially does not recommend, promote or encourage non-adjustment. Rather, it [redacted] The merely descriptive, or informative, nature of this statement is highlighted by contrasting it with the instruction regarding [redacted] The informational statement that [redacted] Again,

[6] Pernix incorrectly states that Alvogen "asserts only that it is not liable for induced infringement because the instructions and data [redacted] in Alvogen's Label were required or suggested by the FDA." (D.A. 120 at 17.) As Alvogen's Expert Dr. Candiotti makes clear in his Rebuttal Report, Alvogen's position is that its Label [redacted]

"[m]erely describing an infringing mode. . . ." without "recommending, encouraging, or promoting an infringing use, or suggesting that an infringing use should be performed." Takeda, 785 F.3d at 630-31 (internal quotation marks and citations omitted); see also Eli Lilly, 845 F.3d at 1368. Of course, [redacted]

Pernix cites only Eli Lilly to support its contention that the statements in Alvogen's Label "are unambiguous on their face and encourage or recommend" infringement. (D.I. 120 at 16-17.) As discussed above, Eli Lilly is inapposite. (Supra at IV.C.1.b.) Unlike Alvogen's Label, the label there directly instructed the administration of folic acid: "Instruct patients on the need for folic acid . . . ." ; "[T]he patient] must also take folic acid . . . ."; "It is very important to take folic acid . . . ." Eli Lilly, 845 F.3d at 1367.

Alvogen's Label does not encourage, recommend or promote administering Alvogen's ANDA Product to [redacted], and Alvogen will therefore not induce infringement of claims 1-4 and 11 of the '760 patent as a matter of law.

V. CONCLUSION

For the reasons set forth above, Alvogen respectfully requests that the Court deny Pernix's Motion for Summary Judgment of Infringement, and instead enter summary judgment of non-infringement of all Asserted Claims in favor of Alvogen.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, David M. Fry, hereby certify that on April 6, 2018, this document was served on the persons listed below in the manner indicated:

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